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08/113,561

08/25/1993

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12/05/2008

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EXAMINER

FOX, DAVID T

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 08/113,561 | Applicant(s) ADAMS ET AL. | |
| | Examiner David T. Fox | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/25/08 & 8/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's Response

In view of the arguments presented in the Response of 25 August 2008 on pages 7-9, regarding Weissinger et al (1988), the Examiner has withdrawn the art rejection over Tomes et al (US 6,258,999). Applicant's amendments of 25 August 2008 have obviated the indefiniteness rejection.

Upon further consideration, the Examiner has applied the following new ground of rejection. The delay in prosecution is deeply regretted.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Enablement

Claims 2-4 and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to stably transformed and fertile maize plants produced by a process comprising the bombardment of regenerable maize cells of the genotype (A188 X B73) with microprojectiles coated with DNA comprising a selectable marker gene, or stably transformed and fertile maize plants produced by a process comprising the electroporation of maize cells with intact cell walls or immature embryos; each process followed by selection of transformed cells on the basis of marker gene expression, and regeneration of whole plants therefrom; does not reasonably provide enablement for claims broadly drawn to stably transformed maize plants of any genotype or produced by any method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to stably transformed and fertile maize plants of any genotype, which may be produced by any unspecified method, including *Agrobacterium*-mediated transformation, electroporation of protoplasts, PEG-mediated protoplast transformation, the imbibition of DNA by dessicated seeds, microinjection, liposome-mediated transformation, and others. See page 56 of the specification, lines 6-14, where multiple methods of plant transformation are contemplated. See also page 134 of the specification, lines 11-13, where pollen-mediated transformation and meristem transformation are also contemplated.

In contrast, the specification only provides guidance for transformed and fertile maize plants produced by a process comprising the bombardment of regenerable maize cells of the genotype (A188 X B73) with microprojectiles coated with DNA comprising a selectable marker gene, or transformed and fertile maize plants produced by the electroporation of walled maize cells or immature maize embryos; each process followed by selection of transformed cells on the basis of marker gene expression, and regeneration of whole plants therefrom.

See, e.g., Table 2, pages 88-89 of the specification, where virtually all of the cell lines that produced fertile transgenic plants were derived from a cross of A188 X B73, and wherein the individual parents A188 or B73 did not produce whole transformed plants or fertile transformed plants. Crosses of A188 with other parents did not produce fertile transformed plants. The only other genotype which produced fertile transgenic plants was AT824, which was characterized as a B73-"derived" genotype (see, e.g., page 92 of the specification, lines 16-18). However, no guidance is provided regarding

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the other parental genotypes utilized in its derivation. See also pages 89-92 and 93-95 of the specification, Examples 1-2 and 4-6, where several other (A188 X B73)-derived cell lines were obtained, including Hi-II.

Moreover, Applicant admits that several of the previously recited transformation methods, namely those involving *Agrobacterium* or protoplasts, are not "preferred" (see, e.g., page 134 of the specification, lines 10-11). Furthermore, the specification only provides guidance for two transformation methods which generate whole, transformed fertile maize plants. The first method involved the bombardment of regenerable cultured maize cells with microprojectiles coated with DNA (see, e.g., Examples 8, 10-12, 16-17, 19-22, and 25-26; specification pages 136-137, 139-140, 145-146, 153-155, 157, 159-161, and 167-169).

The second method involved the electroporation of walled maize cultured cells or immature embryos (see, e.g., Examples 13-14 and 23-24; specification pages 146-149, 161-162, and 164-167). This method was disclosed in a PCT application published in 1992, and so was not available to the skilled artisan as of the 17 April 1990 filing date of the first parent application, or the 09 August 1990 filing date of the second parent application (see, e.g., page 135 of the specification, lines 7-9).

A single example using a third method, silicon fiber-mediated transformation, was not evaluated for the production of whole plants (see, e.g., Example 15, specification pages 149-150). This method was also not disclosed in the two prior parent applications.

No guidance is provided for the use of any other maize genotype; any other method of transformation including protoplast transformation, *Agrobacterium*-mediated transformation, seed desiccation/imbibition mediated transformation, pollen-mediated transformation, microinjection, liposome-mediated transformation, meristem transformation; or transformation in the absence of selection.

Potrykus (Bio/Technology) summarizes the state of the plant transformation art as of June 1990, a few months after Applicant's effective filing date of January 1990. Potrykus teaches that transformation of plants of the cereal family (which encompasses maize) is unpredictable, due to the difficulty in obtaining or identifying cells which are competent for both transformation and regeneration into whole plants.

Potrykus further teaches that transformation methods used for other crops, such as *Agrobacterium*-mediated transformation, are unsuccessful when applied to cereal crops. Potrykus also teaches that other non-exemplified methods such as microinjection, liposome-mediated transformation, imbibition of desiccated seeds, or pollen-mediated transformation have been unsuccessful regarding the obtention of stably transformed plant cells or whole plant regeneration therefrom; while techniques such as protoplast electroporation have resulted in the obtention of transformed but sterile plants.

Potrykus also teaches that protoplast-mediated methods of transformation, such as direct gene transfer or PEG-mediated protoplast incubation, are hampered by the limited availability of techniques and media for regenerating whole plants from

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protoplasts. See, e.g., Potrykus, pages 536-537, Figures 1-23; page 538, column 1, bottom paragraph, column 2, items 3 and 4; page 539-541.

Armstrong et al (1985, *Planta*, submitted by Applicant 15 August 2000) teach that the establishment of regenerable maize callus is genotype-specific and limited to maize inbred line A188 (see, e.g., page 207, paragraph bridging the columns; page 210, paragraph bridging the columns; and page 213, column two, top paragraph).

Rhodes et al (1988, submitted by Applicant 18 October 2004 as Exhibit I) teach that transformed maize plants obtained from transformed A188 protoplasts were sterile, in contrast to the instantly claimed fertile maize plants (see, e.g., page 204, Abstract; page 206, column 2, top paragraph).

Weissinger et al (1988, submitted by Applicant 15 August 2000) teach that a particle-bombardment method of maize transformation, utilizing genotypes 3-86-17 or 13-217 derived from B73 or (B73 X G35) respectively, which genotypes were regenerable prior to transformation, failed to produce stably transformed maize cells or plants (see, e.g., page 23, first full paragraph; page 24, top paragraph). Tomes et al (US 6,258,999) teach the derivation of the 3-86-17 and 13-217 genotypes, and also teach the transformation experiments summarized by Weissinger et al, wherein the chloramphenicol acetyl transferase (CAT) gene was introduced, but wherein selection of transformed cells on chloramphenicol-containing medium was not performed (see, e.g., column 6, lines 43-67; column 8, lines 9-15 and 54-67; column 9, lines 1-55; column 10, lines 37-67; column 11, line 65 through column 12, lines 1-3 and 35-59).

Armstrong (1999, Maydica) teach that even nine years after Applicant's invention, maize transformation remained genotype-dependent (see, e.g., page 105, column 1, second full paragraph, first sentence).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop or identify a multitude of non-exemplified maize genotypes which would be both regenerable and transformable, and which would generate fertile plants after transformation. Undue experimentation would have also been required to develop and evaluate a multitude of non-exemplified maize transformation methods for their ability to generate stably transformed and fertile maize plants.

Conclusion

The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest the obtention of stably transformed and fertile maize plants.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 8, 2008

/David T Fox/

Primary Examiner, Art Unit 1638

/George C. Elliott, Ph.D./

Director, Technology Center 1600

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